

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

June 22, 1998

MEMORANDUM

SUBJECT: Policy Statement on Designation and Qualifications of a Quality Assurance Officer for Environmental Data Operations at Federal Facilities in United States Environmental Protection Agency (EPA) Region 9

FROM: Nora McGee, Assistant Regional Administrator
Policy and Management Division, PMD-3

TO: Environmental Program Managers
National Priority List Federal Facilities in EPA Region 9

Purpose

This memorandum articulates the Region's position on the need to designate a quality assurance officer to oversee environmental data operations at federal facilities. In addition, a reliable QA/Quality Control(QC) structure which the Region believes a quality system must have, is described. The Region believes this position is consistent with its role as an oversight Agency and as a partner with federal facilities in protecting human health and the environment.

Background

An EPA Office of Inspector General (OIG) report of Department of Defense Superfund sites in Region 9 estimated that \$5.5 million of environmental data were rejected and a 2 ½ year delay in cleanups was caused by inadequate QA oversight system of laboratory data. Another OIG report on nine federal facility Superfund sites in USEPA Regions 8, 9, and 10 estimated that over eleven million dollars were spent on rejected analyses, resampling, and associated costs that could have been avoided through the use of effective quality assurance (QA) oversight systems.

A QA system is an integrated program of management activities involving planning, implementation, assessment, and reporting to ensure data are of the type and quality needed; this QA system should be documented in a quality assurance project plan (QAPP). The QAPP defines in detail how specific QA and quality control (QC) activities will be implemented during the relevant project, and identifies a quality assurance officer (QAO). The QAO is responsible for implementation, maintenance, auditing, and oversight of the QA system, performs field and laboratory audits, ensures corrective actions for data quality problems are effectively taken and documented, and verifies the QA system is in accordance with the QAPP.

Despite 18 months of active effort by the Region to implement the OIG recommendation to "Ensure quality assurance officers are appointed in a timely manner and that they are government employees ..." for federal facilities, full implementation has not occurred. The Region strongly believes this creates vulnerabilities in data collection operations, as an

appropriate QAO is an integral and inherent part of the QA system. The Region believes an inadequate project QA system can result in data of inadequate quality for environmental decisions.

The Region strongly supports the OIG recommendation that the QAO must be a government employee for all federal facility data operations. This is the Region's conclusion based on an assessment of the functional requirements of a QAO and the practical state of the use of contractors by federal facilities to perform data operations. There are three related rationales for this, which may be traced back to Agency functional requirements. First, a QAO must make judgements and offer opinion on data operations performed by or on behalf of the Government, and hence is performing an inherently Governmental function. Secondly, a QAO must be able to perform independent assessments, which requires that the QAO not be part of the organization which performed, or be accountable for, the work being assessed. Third, a QAO must have no interest other than ensuring and substantiating the quality of work performed by or on behalf of the Government, and hence cannot have a conflict of interest or an appearance of conflict of interest.

This policy is based on the Region's interpretation of the existing Agency QA manual and EPA Order 5360.1, in conjunction with American National Standard ANSI/ASQC E-4-1994, and is consistent with the QAO recommendation made in the OIG report *Environmental Data Quality at DOD Superfund Sites in Region 9*.

Policy

Scope

Environmental data collection activities performed by federal facilities in EPA Region 9, including work performed under Federal Facilities Agreements (FFAs).

Statement of Policy

QAPPs will be reviewed for designation of a QAO who:

- (1) Is a single point-of-contact for all quality assurance activities;
- (2) Has the necessary skills, knowledge, and independence to fulfill the duties;
- (3) Is a federal government employee ensuring implementation, review, maintenance, and documentation of a QA system and activities performed by the QA system with the following attributes:
 - (3a) Conducts system reviews of environmental data collection activities to ensure that sound quality assurance is being practiced which is in accordance with the QAPP;
 - (3b) Has unrestricted access to programs, managers, and relevant documents;
 - (3c) Has organizational freedom and authority to identify problems and propose recommendations for resolving problems, and then independently confirm implementation of corrective actions;
 - (3d) Does not have a conflict or an appearance of conflict of interest in carrying out designated responsibilities; and

(3e) Has ability to perform audits for conformance to and interpret relevant standards including QA system policies and requirements, consensus standards, and regulatory certification program requirements, especially those standards used by the Agency responsible for the data collection process being overseen and those of the regulatory Agencies performing oversight.

Further, the Region believes that a QAPP that does not identify an appropriate QAO constitutes a serious vulnerability in the project QA system, and therefore potential data quality problems exist.

Further guidance on designing a QA system may be found in the following documents:

U.S. Environmental Protection Agency, *Environmental Data Quality at DOD Superfund Sites in Region 9*, EPA Office of Inspector General Report E1SKF5-09-0031-5100505, September 1995

U.S. Environmental Protection Agency, *EPA Quality Manual for Environmental Programs*, EPA Quality Assurance Division, September 1997

California Military Environmental Coordination Committee, *Best Practices for the Detection and Deterrence of Laboratory Fraud*, March 1997

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995

U.S. Environmental Protection Agency, *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (QA/R-5)*, Office of Research and Development, August 1994